



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/021,577	12/12/2001	Paul O. Sheppard	00-87	1443

7590 08/14/2003

Phillip B.C. Jones, J.D., Ph.D.  
ZymoGenetics, Inc.  
1201 Eastlake Avenue East  
Seattle, WA 98102

EXAMINER

KAM, CHIH MIN

ART UNIT

PAPER NUMBER

1653

DATE MAILED: 08/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/021,577	<b>Applicant(s)</b> SHEPPARD ET AL.	
	<b>Examiner</b> Chih-Min Kam	<b>Art Unit</b> 1653	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-12 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____.  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other:  |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U. S. C. 121:
  - I. Claims 1 and 12, drawn to an isolated polypeptide comprising the amino acid sequence of SEQ ID NO:2, or a composition comprising the polypeptide, classified in class 530, subclass 350.
  - II. Claims 2-8, drawn to an isolated nucleic acid that encodes a zsnk 13 polypeptide, a vector comprising the nucleic acid, a recombinant host cell comprising the vector, or a method of producing zsnk 13 polypeptide, classified in class 536, subclass 23.5, and class 435, subclasses 320.1 and 325.
  - III. Claims 9 and 10, drawn to an antibody, which specifically binds to the polypeptide comprising the amino acid sequence of SEQ ID NO:2, classified in class 424, subclass 130.1.
  - IV. Claim 11, steps (a) and (b), drawn to a method of detecting the presence of zsnk 13 gene expression product such as RNA in a biological sample using a zsnk 13 nucleic acid probe, classified in class 435, subclass 6.
  - V. Claim 11, steps (a') and (b'), drawn to a method of detecting the presence of zsnk 13 gene expression product such as polypeptide in a biological sample using the antibody that specifically binds to a polypeptide of SEQ ID NO:2, classified in class 424, subclass 130.1.
2. The inventions are distinct, each from the other because of the following reasons:

The protein of Invention I is related to the nucleic acid, the vector and the host cell of Invention II because the protein can be produced by the expression of the nucleic acid in the host cell. The inventions are distinct because they are physically and functionally distinct chemical entities and the protein can be made by another process such as isolation procedure from natural source or chemical synthesis.

The protein of Invention I is related to the antibody of Invention III by virtue of being the cognate antigen, necessary for the production of the antibody. The inventions are distinct because they are physically and functionally distinct chemical entities and because the protein can be used in another and materially different process from the use for production of the antibody such as to assay or purify the cognate receptor of the protein or in assays for the identification of agonists or antagonists of the receptor protein.

The method of Invention II and the product of I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the protein as claimed can be isolated from natural source or made by chemical synthesis.

The product of Invention I is distinct from the methods of Inventions IV and V because the product of Invention I can be neither made by nor used in the methods of Inventions IV and V.

Art Unit: 1653

The nucleic acid of Invention II is distinct from the antibody of Invention III because the products of two inventions are physically and functionally distinct chemical entities, and the antibody of Invention III cannot be made by the product of Invention II.

The product of Invention II and the method of Invention IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the nucleic acid of Invention II can be used for producing the protein recombinantly.

The product of Invention II is distinct from the methods of Invention V because the product of Invention I can be neither made by nor used in the method of Invention V.

The product of Invention III is distinct from the methods of Inventions II and IV because the product of Invention III can be neither made by nor used in the methods of Inventions II and IV.

The product of Invention III and the method of Invention V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the antibody of Invention III can be used to isolate the polypeptide by affinity chromatography.

Art Unit: 1653

The methods of Inventions II, IV and V are distinct from each other because the method steps, the materials used and the outcome of the process are wholly different, therefore Inventions II, IV and V are patentably distinct.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their recognized divergent subject matter and different classification, and because inventions I-V require different searches but are not co-extensive, examination of these distinct inventions would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

A telephone call was made to Michelle Johnson on August 11 to request an oral election to the above restriction requirement, but did not result in an election being made.

Art Unit: 1653

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (703) 308-9437. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D. *CMK*  
Patent Examiner

\*\*\*

August 11, 2003

*Christopher S. F. Low*  
CHRISTOPHER S. F. LOW  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1800